


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 443294GA	FOR FURTHER ACTION		See Form PCT/PEA416
International application No. PCT/EP2004/004125	International filing date (<i>day/month/year</i>) 19.04.2004	Priority date (<i>day/month/year</i>) 25.04.2003	
International Patent Classification (IPC) or national classification and IPC B01L3/00, C12Q1/68, G01N1/28			
Applicant NOVEMBER AKTIENGESELLSCHAFT GESELLSCHAFT FJR ...			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> <i>sent to the applicant and to the International Bureau</i> a total of 9 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 19.11.2004		Date of completion of this report 27.09.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Hocquet, A Telephone No. +31 70 340-2928	



**INTERNATIONAL PRELIMINARY REPORT
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International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-60 as originally filed

Claims, Numbers

1-53 received on 10.09.2005 with letter of 09.09.2005

Drawings, Sheets

1/7-7/7 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	33-53
	No: Claims	1-32
Inventive step (IS)	Yes: Claims	
	No: Claims	1-53
Industrial applicability (IA)	Yes: Claims	1-53
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

The following documents are referred to in this report:

- D1 : US 5 229 297 a (SEABERG LEONARD J ET AL) 20 July 1993
- D2 : US 4 889 692 a (HOLTZMAN MARC E) 26 December 1989
- D3 : US 2002/018998 A1 (STEINBISS JOACHIM ET AL) 14 February 2002
- D4 : US 4 585 623 a (CHANDLER HOWARD M) 29 April 1986
- D5 : WO 03/031275 a (SIGNATURE BIOSCIENCE INC) 17 April 2003
- D6 : US 6 197 595 B1 (FODOR STEPHEN P a ET AL) 6 March 2001

Re Item V

- 1 When compared to any of the documents D1, the subject-matter of claim 1 is not new (Article 33(2) PCT), because D1 discloses in combination all the features defined in that claim:
Document D1 discloses devices with chambers with pistons (figures 9-14) for reversibly changing their volumes connected by channels and with a sealable inlet port 22 (see c 13, l 63-69) which constitutes a connector with flow regulating means connected to a chamber (eg figure 14). The channel themselves can be provided with flow regulating means in form of pinch valves P1-P5 (c 12, l 19-35). D1 mentions that a chamber connected to the channels can be filled with a reagent sealed in form of prepackaged ampules (c 15, l 63-66).
- 2 The subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT over document D2:
 - 2.1 Document D2 discloses chambers A-F with pistons for reversibly changing their volume, the chambers being connected via channels 36 in a connector which acts as a rotating valve regulating the flow between the chambers. D2 does not disclose the incorporation of binding material in the chambers. The purpose of the device described in D2 is to prepare samples of samples and avoid contamination during this preparation. Two examples of specific preparation are given (filtration by a filter contained in one of the chamber) or liquid-liquid extraction, but it is clear to the reader that the structure of D2 (piston chambers connected by valve channels) is not limited to any specific mechanical or chemical treatment of the sample (D2, c 4, l 43-45), provided this chemical or mechanical treatment can take place in a piston chamber. The device of D2 contains at least 3 chambers and the chambers are connectable to

- the channels according to the position of the valves (see figures 2,4,7)
- 5.1 Claim 1 differs from D2 by the provision in one of the chamber of a reactant prior to use. But providing a prepackaged sealed reactant in one of the chamber is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to bring the required reactants to the device.
- 2.1 When compared to D1, the subject-matter of claim 32 is not new (Article 33(2) PCT), because D1 discloses a device with a base plate with channels (figure 14) and a detachable chamber in form of a pre-packaged sealed ampule filled with reagents (c 15, l 63-66) is connectable (by insertion in a compartment) to the channel.
- 2.2 When compared to D4, the subject-matter of claim 32 is not new in the sense of Article 33(2) PCT, because D4 discloses a baseplate with a channel 20 (see figure 2) provided with one way valves 30. A chamber (syringe 40 in figure 1) filled with a reactant (sample) and sealed (sample retained by capillarity in the space between its end and the notch 42 and sealed by plunger 43) is connectable to the channel before to use (figure 1).
- 3 As long as it relates to the use of a known device, the subject-matter of claim 33 does not involve an inventive step in the sense of Article 33(3) PCT because the step of moving back and forth a sample solution so that it contacts and binds to a material is known either from D3 (paragraphs 59 and 60) or from D6 (from column 25, line 63).
- 4 The subject-matter of dependent claims 2-31 or 34-53 does not involve an inventive step in the sense of Article 33(3) PCT, because their features have already been employed for the same purpose in similar devices for preparing analytes (see relevant passages cited in the Search Report):
- 4.1 Document D3 discloses in figure 2 an arrangement with two chambers connected by a channel, plungers for changing the volumes of the chambers and a flow regulation means(3-way valve) in the channel linking the two chambers.
- 4.2 Document D5 discloses a collapsible chamber connected to a piston chamber via a piercing needle, the flow being controlled between the two chambers by a septum connected to the collapsible chamber, the septum being thus a means of flow

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(SEPARATE SHEET)**

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regulation.